



Chicago, Illinois USA 60618-5935  
Phone: 773-975-3975 ext.3495  
Fax: 773-868-3558  
www.hu-friedy.com

K100401

1071

## 510(k) SUMMARY

**NAME & ADDRESS:** HU-FRIEDY MFG. CO., INC.  
3232 N. ROCKWELL STREET  
CHICAGO, IL 60618  
(773) 975-3975 EXT. 3495  
FAX (773) 868-3558

**MAR 30 2010**

**510(k) NOTIFICATION (21 CFR 807.90(e))**  
**SUBMISSION TYPE: TRADITIONAL 510K**

**SUBMITTER: HU-FRIEDY MFG. CO. INC.**

**DATE PREPARED: 12/16/2009**

**CONTACT: MARIA VRABIE- MANAGER OF REGULATORY AFFAIRS**

**TRADE NAME: HU-FRIEDY® SWERV<sup>3</sup> MAGNETOSTRICTIVE ULTRASONIC SCALER**

**CLASSIFICATION NAME: ULTRASONIC SCALER**

**REGULATION NUMBER: 21.CFR, 872.4850**

**REGULATORY DEVICE CLASS- II**

**PRODUCT PANEL & CODE: 76 ELC**

**PREDICATE DEVICES: K970123 & K033705**

**DESCRIPTION:** The Swerv<sup>3</sup> Magnetostrictive Ultrasonic Scaler is a portable stand alone scaler, handpiece and foot control. The Swerv<sup>3</sup> Magnetostrictive Ultrasonic Scaler operates at 25 kHz and 30 kHz and accepts voltage inputs between 100-240V.

The available power output is segmented into two overlapping adjustable power zones to assist the user in selecting the recommended power setting for a selected ultrasonic insert. The power and water controls of the Swerv<sup>3</sup> Scaler are located in the control unit.

**INTENDED USE:** This device generates ultrasonic vibrations intended for ultrasonic procedures: 1.) General Supra and Subgingival scaling applications; 2.) Periodontal debridement for non-surgical treatment of Periodontal diseases.

**TECHNOLOGICAL CHARACTERISTICS:** The Swerv<sup>3</sup> Magnetostrictive Ultrasonic Scaler plugs into an ordinary electrical outlet and converts the AC current into high frequency electro-mechanical vibrations. The Swerv<sup>3</sup> Scaler features a patented switching mechanism to support the use of either 25 kHz or 30 kHz inserts. Therefore, the scaling system accepts both Hu-Friedy 25 kHz and 30 kHz Ultrasonic Inserts. Hu-Friedy has 510(k) market clearance for our 25 kHz and 30 kHz Ultrasonic Inserts/Tips (K953919 and K912473). The addition of the Swerv<sup>3</sup> Scaler will complete our Magnetostrictive ultrasonic scaling product line and offer customers a complete package for their scaling needs.

Results of in-house testing with Hu-Friedy ultrasonic inserts (ref. K953919 and K912473) in the Swerv<sup>3</sup> Scaler demonstrated that they performed within recommended specifications. Moreover, analysis of frequency and stroke data demonstrated equivalency to predicated devices in the market and that the Swerv<sup>3</sup> scaling system meets ISO 22374 requirements. EMC and Safety testing conducted by Underwriters Laboratories on the Swerv<sup>3</sup> System have demonstrated compliance with the international requirements for this device. The performance testing performed on the Swerv<sup>3</sup> Magnetostrictive Ultrasonic Scaler demonstrates the safety and efficacy for its intended use.

All the materials used in the device have been used in legally marketed Hu-Friedy devices or found to be safe for dental use. Hu-Friedy believes the unit to be substantially equivalent to the Dentsply<sup>®</sup> Cavitron SPS PLUS (30 kHz) and Dentsply Cavitron Bobcat (25 kHz) Ultrasonic Scalers.



## DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

HU-Friday MFG. Company, Incorporated  
C/O Ms. Casey Conry  
Responsible Third Party Official  
Underwriters Laboratories, Incorporated  
1285 Walt Whitman Road  
Melville, New York 11747

MAR 30 2010

Re: K100401

Trade/Device Name: Swerv<sup>3</sup> Magnetostrictive Ultrasonic Scaler System  
Regulation Number: 21CFR 872.4850  
Regulation Name: Ultrasonic Scaler  
Regulatory Class: II  
Product Code: ELC  
Dated: March 12, 2010  
Received: March 16, 2010

Dear Ms. Conry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Anthony D. Watson". To the right of the signature, the letters "for" are handwritten in a smaller, cursive font.

Anthony D. Watson, B.S., M.S., M.B.A.  
Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



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K100401 101

### Indications for Use

510 (k) Number (if known: K100401)

Device Name: Swerv<sup>3</sup> Magnetostrictive Ultrasonic Scaler System

#### INTENDED USE:

This device generates ultrasonic vibrations intended for ultrasonic procedures: 1.) General Supra and Subgingival scaling applications; 2.) Periodontal debridement for non-surgical treatment of Periodontal diseases.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

Delegation for Dr. K.P. Mulligan  
RSB: BRS for Dr. K.P. Mulligan  
(Division Sign-Off)

Concurrence of CDRH, Office of Device Evaluation

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K100401 An ISO 13485 International Company